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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

AFREMOVA, V

ART UNIT	PAPER NUMBER
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1651

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DATE MAILED:

06/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/674,280

Applicant(s)

Nakamura et al.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 18, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

Claims 1-6 are pending and under examination.

Claim Rejections - 35 U.S.C. § 112

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite with regard to “a liquid reaction system” in the lack of clear definitions. It is uncertain as claimed whether liquid is required during all or both stages. It is uncertain as disclosed what amounts of water are intended for the claimed method. This limitation is particularly uncertain since the claimed method is further drawn to the use of either “submerged culture” (see claim 5) or some vegetable material in a “solid state” (claim 6).

Claim 2 is indefinite because it is uncertain what criteria are intended for determining 10% to 60% of the total period of time as claimed. It is uncertain what is considered as “completion of the reaction” or what is a final product as intended. Thus, the metes and bounds of the claimed method can not be determined.

Claim 4 is indefinite with regard to amounts of reducing sugar. It is uncertain whether the claimed amount is a final result at the moment of completion of enzymatic hydrolysis of vegetable material using a fungal culture. Or whether the amount of reducing sugar is actually adjusted by addition or removal of some sugars/materials or some temperature manipulations. The claimed invention is a method of making a product but the claimed method does not comprise active step

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written in an active voice. Thus, it is uncertain what steps are performed in order to obtain 5% of reducing sugars as claimed.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,045,819 [A] or WO 95/28853 [N].

The claims are directed to a method for producing hydrolyzed protein from vegetable material wherein the method comprises step of mixing fungal culture with vegetable material such as wheat gluten or de-fatted soybean, step of conducting first stage fermentation at temperature 15-39°C with aeration and step of conducting second stage fermentation at temperature 40-60°C. Some claims are further drawn to use of submerged culture or semi-liquid reaction culture.

WO 95/28853 [N] discloses a method for producing hydrolyzed protein or a seasoning sauce (see abstract or see page 9, par. 2 and par. 4 or see page 11) wherein the method comprises step of mixing fungal culture such as koji mold *Aspergillus oryzae* with vegetable material such as wheat gluten, step of conducting first stage fermentation at temperature 30-35°C with aeration or mixing and step of conducting second stage fermentation at temperature 40-45°C. The cited method encompasses the use of liquid or submerged or semi-liquid reaction by teaching the use of

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liquefied gluten suspension or spore suspension (page 9, par. 2, line 3 or line 14). The cited reference suggests the use of defatted soybean (page 1, par. 1) in a method for producing hydrolyzed protein. The resulting product has a light color (abstract).

US 6,045,819 [A] discloses a method for producing hydrolyzed protein from vegetable material wherein the method comprises step of mixing fungal culture such as various koji molds including *Aspergillus oryzae* (col.10, lines 30-39) with vegetable material such as de-fatted soybeans (col. 9, lines 55-57), step of conducting first stage fermentation at temperature 28-30°C with aeration (col.9, line 60) and step of conducting second stage fermentation at temperature 30-60°C (col. 10, line 66) or 50°C (col. 11, line 56) or 58 °C (col. 12, line 2). The cited patent teaches the use of liquid culture or addition of water in to reaction system (col. 11, lines 66-67) or at least some amount of water (col. 8, line 65) in a method for producing hydrolyzed protein. The cited method encompasses the use of pasteurization or sterilization of vegetable material prior to fermentation by teaching "cooking" or heating soybeans (Fig. 1). And the cited method encompasses pulverization of vegetable material prior to fermentation by teaching the use of soy powder or small granules (see col. 9, lines 11-20, for example). With regard to hydrolysis completion and/or hydrolysis time the cited patent teaches that these parameters are selected depending the type of particular koji mold used in the process (col. 14, lines 27-30).

The cited methods are considered to anticipate the claimed invention because they appear to comprise all claimed active steps and structural elements of the claimed process.

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Claim Rejections - 35 U.S.C. § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 6,045,819 [A] or WO 95/28853 [N] in the light of US 3,655,396 [B], JP 50019996 [O] and/or Muramatsu et al.[U].

The claims 1-3 and 4 as explained above. The claim 5 is further drawn to amounts of reducing sugar such as 5% or less in the final product.

The references US 6,045,819 [A] and WO 95/28853 [N] are relied upon as explained above for a disclosure of a method for producing hydrolyzed protein from vegetable material by using fungal cultures and two temperature stage fermentations. The cited methods are silent with regard to amounts of reducing sugars in a final product.

The references US 3,655,396 [B], JP 50019996 [O] and Muramatsu et al. [U] disclose methods for producing hydrolyzed protein from vegetable material by using koji molds and various fermentation temperatures such as 25-30°C {see abstract JP 50019996 [O]} or 33°C {see US 3,655,396 [B] example 3} or 50-60°C {see abstract Muramatsu et al.[U]} wherein the amounts of reducing sugars are/are adjusted to amounts less than 5%. For example: 2.35% {see

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abstract JP 50019996 [O]} or 1.5% {see US 3,655,396 [B] example 3} or absent {see abstract Muramatsu et al.[U]}.

Therefore, the cited reference US 6,045,819 [A] and WO 95/28853 [N] are considered to anticipate the claimed invention since the cited methods of US 6,045,819 [A] or WO 95/28853 [N] comprise identical active steps and identical structural elements as the claimed methods. Thus, the final product at the completion of identical reactions would inherently be identical.

In the alternative, even if the claimed method is not identical to the referenced methods of US 6,045,819 [A] or WO 95/28853 [N] with regard to some unidentified steps or structural elements or some characteristics of fungal cultures, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced methods are likely to inherently produce the same or substantially similar products at the completion of reaction/fermentation particularly in the light of teaching of US 3,655,396 [B], JP 50019996 [O] and/or Muramatsu et al.[U] which demonstrate that the use of koji mold preparation/fermentation at the same temperature from 25°C to up to 60°C or temperature either 25-30°C or 55-60°C are characterized by the same amounts of reducing sugars produced from vegetable materials such as less than 5% as the claimed resulting preparation. In addition, the cited US '819 teaches that hydrolysis of vegetable proteins depends on a particular type of koji mold which is employed for hydrolysis (col. 14, line 29). And the claimed invention appears to employ an identical koji mold such as *Aspergillus oryzae* (see specification page 24) as the cited methods. Thus the claimed method would have been obvious to those skilled in the art within the meaning of U.S.C. 103.

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Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of clear evidence to the contrary.

Claim Rejections - 35 U.S.C. § 103

Claims 1-6 rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,045,819 [A] or WO 95/28853 [N] in the light of US 3,655,396 [B], JP 50019996 [O] and/or Muramatsu et al. [U] as applied to claims 1-5 above, and further in view of US 5,888,561 [C].

The claims 1-5 as explained above. The claim 6 is further drawn to pulverization and sterilization of vegetable material prior to fungal fermentation.

The cited references are relied upon as explained above. The are not particularly clear with regard to pulverization and sterilization of vegetable material prior to fermentation.

The cited US 5,888,561 [C] clearly teaches the use of pulverization or extruding and sterilization of vegetable material prior to koji mold fermentation as a conventional procedure in the method for producing hydrolyzed proteins (example 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the cited methods of US 6,045,819 [A] or WO 95/28853 [N] by adding steps drawn to pulverization and sterilization of vegetable material prior to fermentation with a reasonable expectation of success in producing hydrolyzed proteins because pulverization and sterilization of vegetable material prior to fermentation are well known and conventional procedures in the methods for koji mold fermentations [C]. Thus, the claimed

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invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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June 26, 2001.



**SANDRA E. SAUCIER
PRIMARY EXAMINER**